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I also certify that the application is now proceeding in the name as identified herein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

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Dated 4 November 2003

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GB0215904.4

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of

OPTINOSE AS,  
Lokkaskogen 18c,  
0773 Oslo,  
Norway

Incorporated in Norway,

[ADP No. 08042905001]

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An Executive Agency of the Department of Trade and Industry

Patents Form 1/77

THE PATENT OFFICE

THE  
Patent  
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- 9 JUL 2002

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## Request for grant of a patent

(See the notes on the back of this form. You can also get  
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09 JUL 2002

0215904.4

The Patent Office

Cardiff Road  
Newport  
Gwent NP9 1RH

Fee: £0 - (£25 Faxback)

1. Your reference

SJNG/44854.GB01

2. Patent application number

(The Patent Office will fill in this part)

10JUL02 E732111-1 D01631

E01/7700 A 00-0215904.4

3. Full name, address and postcode of the or of  
each applicant (underline all surnames)

Team Holdings (UK) Limited

Cokenach  
Barkway  
Hertfordshire  
SG8 8DL

08033557001

Patents ADP number (if you know it)

If the applicant is a corporate body, give the  
country/state of incorporation

United Kingdom

SECTION 23 (1977 ACT) APPLICATION FILED 14/10/03

4. Title of the invention

Drug Delivery System and Method

5. Full name, address and postcode in the United  
Kingdom to which all correspondence relating  
to this form and translation should be sentReddie & Grose  
16 Theobalds Road  
LONDON  
WC1X 8PLFry Heath & Spence &  
The Pables  
Massetts Road  
Horley, Surrey  
RH6 4D9

Patents ADP number (if you know it)

91001  
052 802730016. If you are declaring priority from one or more  
earlier patent applications, give the country  
and the date of filing of the or of each of these  
earlier applications and (if you know it) the or  
each application number

Country

Priority application  
(if you know it)Date of filing  
(day/month/year)7. If this application is divided or otherwise  
derived from an earlier UK application,  
give the number and the filing date of  
the earlier application

Number of earlier application

Date of filing  
(day/month/year)8. Is a statement of inventorship and of right  
to grant of a patent required in support of  
this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or  
b) there is an inventor who is not named as an  
applicant, or  
c) any named applicant is a corporate body.  
See note (d))

YES

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## Patents Form 1/77

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## Continuation sheets of this form

Description 2

Claim(s)

Abstract

Drawing(s)

3 only

10. If you are also filing any of the following, state how many against each item.

## Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Reddie &amp; Grose

Date

9 July 2002

REDDIE &amp; GROSE

12. Name and daytime telephone number of person to contact in the United Kingdom

S J N GOODMAN  
01223 360350

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### Drug Delivery System and Method

The invention relates to a single shot disposable nasal insufflator based on innovative packaging technology.

#### Background

The nasal delivery for a range of powder and liquid drugs has been established for some time and there are a range of existing products on the market which use this method. The oral route for drug delivery is far more prevalent, but there is an increasing amount of research being carried out in the nasal delivery technologies.

'Form, fill and seal' packaging using vacuum forming/laminating and aluminium foil technologies is well established for a range of product types, both in the pharmaceutical sector (including capsule blister packs and sachets for lyophilised drugs) and for a large range of other types of product (e.g. coffee sachets and adhesives). Two compartment pouches with breakable barrier seals between the compartments are well established technologies. Also, in many cases and especially non-pharma applications, 'form fill and seal' plastic products incorporating welded-in injection moulded spouts and caps are commonplace.

#### Summary of the invention

The technology on which protection is sought is the use of a breakable seal in a 'form fill and seal' pouch as the basis of a single use product that will allow the generation of a cloud of powder particles or liquid droplets. A pouch containing liquid or powder would be sealed such that, on the direct or indirect application of pressure, a specific barrier seal will burst such that the now pressurised liquid/powder is expelled through an attached spout or nozzle. The key to the invention is the ability to 'tune' the pressure at which the barrier seal is broken, and to control the characteristics of the subsequent flow of liquid/powder.

In a second aspect, the liquid or powder may be contained in the nozzle prior to delivery, separated from the pouch by the breakable barrier seal. Compression of the pouch increases the pressure therein, which causes the seal to break and delivers the liquid or powder through the nozzle.

Preferably, the pouch may be constructed so that it collapses only when a predetermined external force is applied to it, for example by a user's hand. The pouch may then collapse in a rapid, predetermined way. This may advantageously make the seal break in a more predictable manner.

Advantageously, the interior of the pouch may carry a spike or blade positioned so as to penetrate the seal, or assist rupturing of the seal, when the pouch is compressed, preferably to a predetermined volume. This may rupture the seal at an advantageously predictable pouch pressure.

In the specific applications described, the invention enables the manufacture of a low cost disposable drug delivery device based on manufacturing processes that are, separately, already well established.

Figure 1 shows isometric views of a first embodiment of the invention before and after compression of the pouch.

Figure 2 shows isometric and sectional views of a second embodiment of the invention.

Specific description

In a first embodiment, the invention provides a single shot disposable nasal insufflator drug delivery device (figure 1). This is a foil/vacuum formed 'form, fill and seal' approach whereby failure of a barrier seal requires a certain amount of force to be applied to a pouch which, when released, acts as the motive force driving the dose out through the nozzle. In this case the drug within the pouch could be in powdered form, and the spout/nozzle would be of a design appropriate for the delivery of the drug to the target site. In conjunction with a barrier seal which failed at the required pressure, the nozzle would deliver a dose of powdered drug in to the nasal cavity. Powder particle size would be largely determined by the processing methods but would need to be disagglomerated as required to give the necessary fine particle fraction. In a variation of this embodiment the drug is housed within the nozzle rather than in the pouch prior to delivery.

In a second embodiment, the invention utilises an essentially hemispherical or similar dome form such that, in addition to having a barrier which breaks at a given pressure, the force displacement characteristic of the dome could be tuned to give suddenly at an applied force threshold. The rupturing of the barrier seal could be effected purely by the pressure generated, or by some other mechanism (e.g. a puncturing spike on the inner face of the dome as shown in Figure 2), or both. Figure 2 illustrates a collapsing dome whereby a force is applied to the dome which collapses at a certain threshold. The sudden release causes a 'spike' feature on the underside of the dome to cause or help cause the bursting of the barrier seal, resulting in the dose being expelled through the nozzle.

Alternative implementations of the technology could use variations in the nature of the product contained within the pouch, e.g. liquids of differing densities and viscosities as opposed to powder, with the nozzle geometry and force profile combining to generate a liquid aerosol of liquid droplets that gave optimum effectiveness of drug delivery.

There could also be variations in barrier seal burst pressures, and variations in nozzle types and geometries, to produce a drug delivery device with a range of applications.

The same technology could be used for a range of non-healthcare applications where a one-off controlled release of powder or liquid is required.

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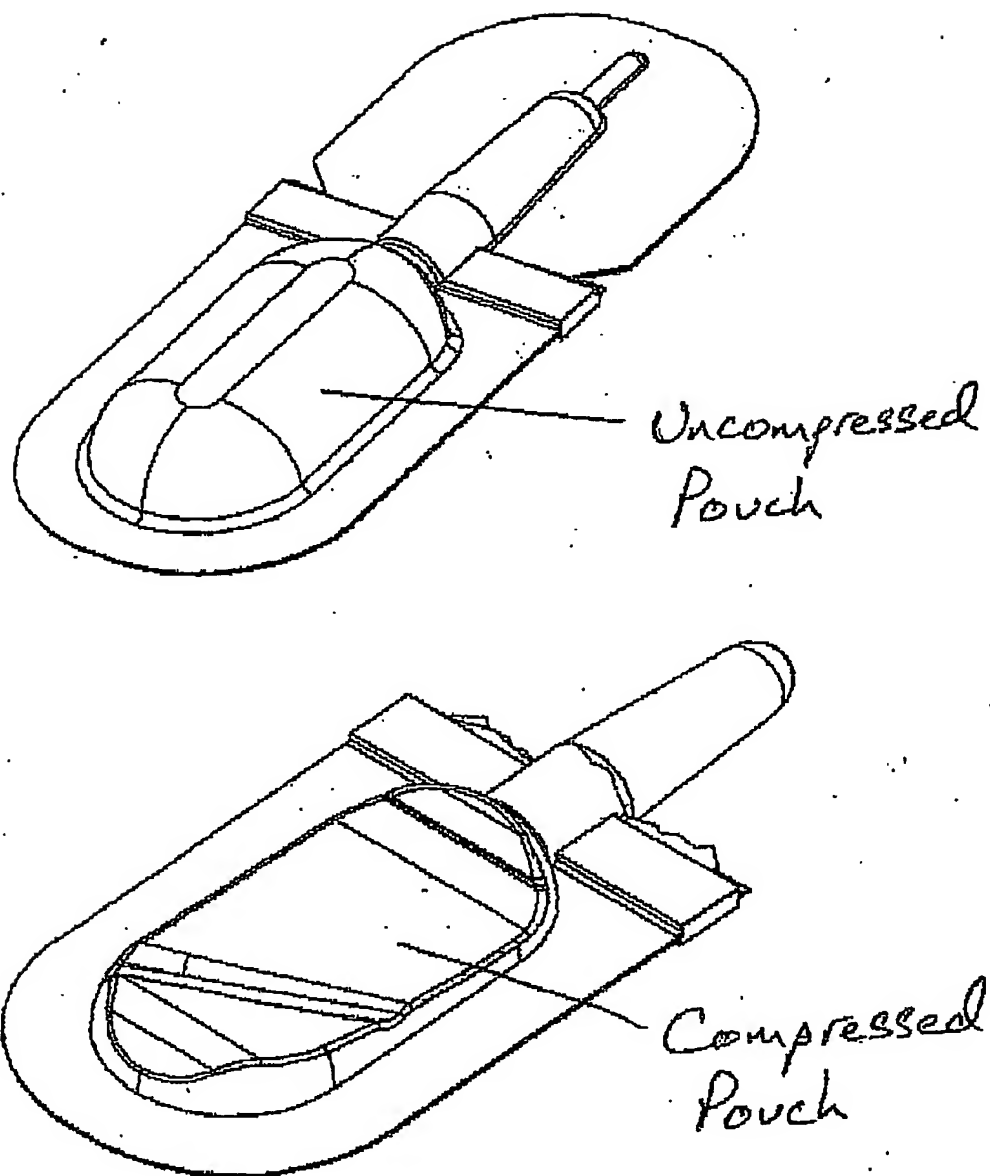


Figure 1

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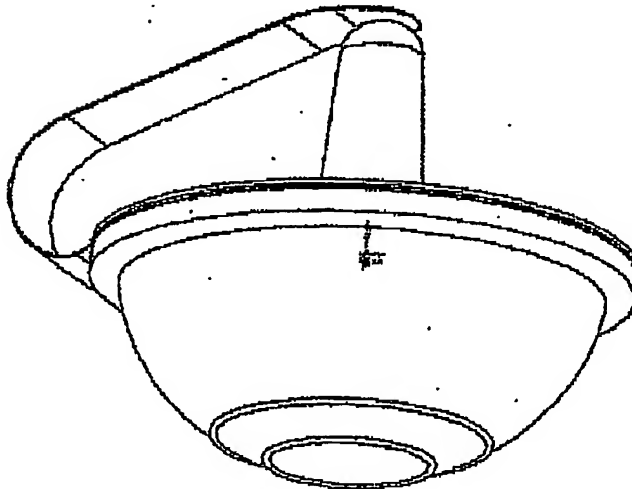
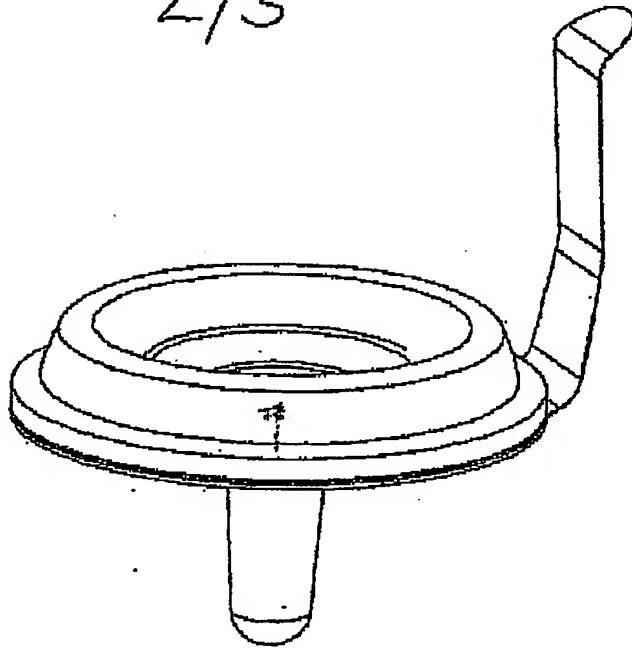


Figure 2 A



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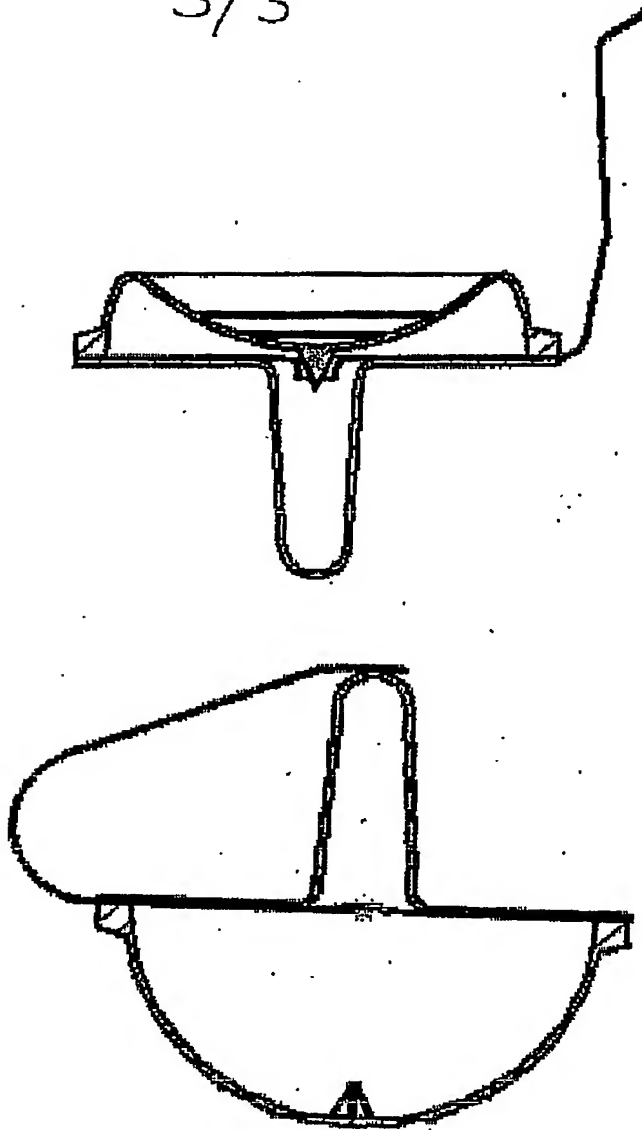


Figure 2b